

Department of Safety of Medicines

04/10/2005

Doc. No. 1714/44/2005

Handal Trade OÜ  
Noole 2-8  
10415 Tallinn  
ESTONIA

**CLASSIFICATION OF THE PREPARATION COLOCYNTH**

Enterprise Handal Trade OÜ has submitted an application to the Pharmaceutical Board to classify the preparation COLOCYNTH. According to the information submitted to the board, Colocynth ointment is of vegetable origin and made from herbs (contains vegetable oils and extracts). The ointment is produced in Egypt. The preparation is for external application, as a massage ointment, for instance.

Pursuant to §6 of the Medicinal Products Act, the Pharmaceutical Board is required to determine, where relevant, whether a substance or a preparation may be deemed to be a medicinal product.

The Pharmaceutical Board already classified the preparation, called Colocynth ointment, on 18 May 2005 on the basis of the application of Eucalypt OÜ. According to the decision (doc. No. 1969/44/2004), Colocynth ointment cannot be deemed a medicinal product for the purposes of §3 of the Medicinal Products Act (Annex 1).

Head of the Department, Professor */Signature/*  
Erkki Palva

Head Dispensing Chemist */Signature/*  
Anne Pesonen

**ANNEX**

Decision of the Pharmaceutical Board. Doc. No. 1969/44/2004

18/05/2005

Dok. nr 1969/44/2004

**CONTENT** Application of enterprise Eucalypt OÜ to classify the following preparation :

**Colocynth ointment**

The preparation is used as a massage ointment to alleviate muscular and extensor muscle tension caused by exercise or physical labour.

**Composition as submitted:** vegetable oils and extracts (*Citrullus colocynthis*, *Olea europea*, *Myrtus communis*, *Sinapis alba*, *Apium graveolens*, *Allium ampeloprasum*, *Raphanus sativus*, *Linum*, *Agrostemma cithago*, *Archis hypogea*, *Sesamum indicum*. Plant extracts: *Majorana hortensis*, *Thymus capitatus*, *Cinnamomum camphora*, *Mentha piperita*, *Rosa*, *Ocimum basilicum*). According to the information submitted to the board, the preparation contains 2.5% of camphor.

**DECISION AND REASONING** Based on the purpose of use and composition, the preparation cannot be regarded as a medicinal product for the purposes of §3 of the Medicinal Products Act.

**APPLICABLE** Sections 3 and 6 of the Medicinal Products Act.

**LEGAL PROVISIONS**

**APPEAL** If this decision is rejected, it may be appealed in Helsinki Administrative Court. The instructions for appeal are attached.

Head, Professor */Signature/*  
Hannes Wahlroos

Head Dispensing Chemist */Signature/*  
Anne Pesonen

**PROCESSING FEE €85**

(Decision No. 1064/2003 of the Social and Health Care Ministry)

**DECISION** Eucalypt OÜ  
Tamme 1-11  
Tallinn  
Estonia

**ANNEX FOR INFORMATION** Instructions for appeal  
Food Board  
Consumer Board  
Customs Board  
Customs Laboratory

If necessary, additional information regarding the decision may be obtained from the Head Dispensing Chemist, Anne Pesonen, phone 09-47 334 336.